

## Food and Drug Administration, HHS

## § 866.3

866.5440 *Beta*-2-glycoprotein III immunological test system.  
866.5460 Haptoglobin immunological test system.  
866.5470 Hemoglobin immunological test system.  
866.5490 Hemopexin immunological test system.  
866.5500 Hypersensitivity pneumonitis immunological test system.  
866.5510 Immunoglobulins A, G, M, D, and E immunological test system.  
866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.  
866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.  
866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.  
866.5550 Immunoglobulin (light chain specific) immunological test system.  
866.5560 Lactic dehydrogenase immunological test system.  
866.5570 Lactoferrin immunological test system.  
866.5580 *Alpha*-1-lipoprotein immunological test system.  
866.5590 Lipoprotein X immunological test system.  
866.5600 Low-density lipoprotein immunological test system.  
866.5620 *Alpha*-2-macroglobulin immunological test system.  
866.5630 *Beta*-2-microglobulin immunological test system.  
866.5640 Infectious mononucleosis immunological test system.  
866.5660 Multiple autoantibodies immunological test system.  
866.5680 Myoglobin immunological test system.  
866.5700 Whole human plasma or serum immunological test system.  
866.5715 Plasminogen immunological test system.  
866.5735 Prothrombin immunological test system.  
866.5750 Radioallergosorbent (RAST) immunological test system.  
866.5765 Retinol-binding protein immunological test system.  
866.5775 Rheumatoid factor immunological test system.  
866.5785 Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) antibody (ASCA) test systems.  
866.5800 Seminal fluid (sperm) immunological test system.  
866.5820 Systemic lupus erythematosus immunological test system.  
866.5860 Total spinal fluid immunological test system.  
866.5870 Thyroid autoantibody immunological test system.  
866.5880 Transferrin immunological test system.  
866.5890 Inter-*alpha* trypsin inhibitor immunological test system.

### Subpart G—Tumor Associated Antigen Immunological Test Systems

866.6010 Tumor associated antigen immunological test system.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 47 FR 50823, Nov. 9, 1982, unless otherwise noted.

### Subpart A—General Provisions

#### § 866.1 Scope.

(a) This part sets forth the classification of immunology and microbiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an immunology and microbiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a microbiology device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17733, May 11, 1987]

#### § 866.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (Premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.